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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,311	04/28/2006	Koh-Ichi Sakata	1603/2	1552

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JENKINS, WILSON, TAYLOR & HUNT, P. A.  
3100 TOWER BLVD., Suite 1200  
DURHAM, NC 27707

EXAMINER
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GUSSOW, ANNE

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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01/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/559,311	SAKATA ET AL.
	Examiner Anne M. Gussow	Art Unit 1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 30 November 2007.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-11 is/are pending in the application.  
 4a) Of the above claim(s) 1-5, 9 and 10 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 6-8 and 11 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/ are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. Claims 6, 7, and 11 have been amended.  
Claims 6-8 and 11 are under examination.
2. The finality of the previous Office Action is withdrawn.
3. The following Office Action contains NEW GROUNDS of Rejection.

***Rejections Maintained/ NEW GROUNDS of Rejection***

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
5. Claims 6-8, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: a step or several steps defining how the protein kinase activity is measured and a result of the determining step, i.e. is an increase or decrease in DNA-dependent protein kinase activity indicative of cancer.
6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 6-8 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The phrase "further screened for cancer" is not supported in the specification as filed. Applicant is required to remove the new matter added to the claims or to specifically point out the location in the specification that provides support for the phrase "further screened for cancer".

8. The rejection of claims 6-8 and 11 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained.

The response filed November 30, 2007 has been carefully considered but is deemed not to be persuasive. The response states that the intention of the presently claimed subject matter is not to predict that a subject will develop cancer, but rather, to provide a method of screening subjects to determine if, based upon DNA-dependent protein kinase activity, a patient is more or less likely to develop cancer (see response page 8).

The response also states that since it is established that DNA-dependent protein kinase is inversely related to genetic mutations and that genetic mutations can lead to

cancer, it is axiomatic that prior to the development of cancer resulting from genetic mutations there must have been present one or more genetic mutations. Stated another way, cancer resulting from one or more genetic mutations cannot develop unless there is first a genetic mutation. Further, based upon the established relationship discussed hereinabove, if genetic mutations are present it is likely that the mutations are due, at least in part, to reduced DNA-dependent protein kinase activity. As such, one of skill in the art will appreciate that the relationship between cancer, genetic mutations and DNA-dependent protein kinase activity exists both pre and post-cancer development (see response pages 9-10).

In response to these arguments, the specification discloses a reduction in protein kinase activity in patients who already have cancer (see example 2), not from samples from patients who have as yet to be diagnosed with cancer, thus, there is no guidance to assist one of skill in the art in predicting the susceptibility of a patient to cancer by measuring protein kinase activity. Additionally, Someya, et al. in post filing date art teaches that there is no significant difference in the amount of protein kinase activity in patients with head and neck cancer, esophageal cancer, or malignant lymphoma compared to normal controls (page 119 and figure 1A, as cited in a previous office action). Therefore, measurement of protein kinase activity is not indicative of cancer.

Regarding the relationship between genetic mutations and cancer, the specification does not correlate and the Someya reference data argues against evidence that the amount of protein kinase activity relates to the amount of genetic mutations and thus the development of cancer. Indeed, applicant's own arguments

state that "the mutations are due, at least in part to reduced DNA-dependent protein kinase activity" (see response page 10). Thus, applicant is admitting that other factors are involved, if not required, to result in a cancer. While genetic mutations are involved in a number of cancers, they are not the sole cause of cancer, nor the sole determinant of whether a person will develop a cancer.

Therefore, after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 6, 8, and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogawa, et al. (EP 1184665A1, published March 6, 2002, as cited in a previous Office Action).

The claims recite a method for assessing a subject's susceptibility to cancer by measuring DNA-dependent protein kinase activity in cells derived from a-test the subject to determine if the subject should be further screened for cancer, wherein the cancer is selected from the group consisting of breast cancer, uterine cancer, and head and neck cancer, wherein the cells are lymphoid cells. The claims also recite a method

for assessing a subject's susceptibility to cancer to determine if the subject should be further screened for cancer, comprising: measuring DNA-dependent protein kinase activity in cells derived from a test subject; and determining susceptibility of the test subject to cancer based upon the measured DNA-dependent protein kinase activity, wherein the cancer is selected from the group consisting of breast cancer, uterine cancer, and head and neck cancer.

Ogawa, et al. teach a method for measuring protein kinase activity in a test sample consisting of the steps of contacting the sample with a substrate peptide phosphorylated by the protein kinase under conditions necessary for the phosphorylation reaction and detecting a change in the phosphorylation level of the substrate peptide based on the change in reactivity of the substrate peptide with an antibody that identifies the phosphorylation site of the substrate peptide (page 3, lines 44-50), wherein the sample is obtained from tissue samples, blood, urine, body fluids, sweat, saliva, and body secretions such as milk (page 8 lines 7-10). Since the only active step of the claimed method is measuring protein kinase activity, and Ogawa, et al. teach measuring protein kinase activity, upon further consideration this rejection has been reinstated and all the limitations of the claims have been met.

### ***Conclusion***

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

January 3, 2008  
/Larry R. Helms/  
Supervisory Patent Examiner